

Food and Drug Administration, HHS

§ 431.53

Services, 5600 Fishers Lane, Rockville, MD 20857.

Form

- 1 Application for exemption for storage.
- 2 Application for exemption for processing.
- 3 Application for exemption for labeling.
- 4 Application for exemption for manufacturing use.
- 7 Request for check tests and assays or certification of a batch of _____ (the blank to be filled in with the name of the antibiotic drug).
- 8 Application for exemption for repackaging.
- 9 Request for supplemental certification of a batch of an antibiotic drug.

[39 FR 18934, May 30, 1974, as amended at 40 FR 28052, July 3, 1975; 41 FR 10886, Mar. 15, 1976; 50 FR 7516, Feb. 22, 1985; 50 FR 8997, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§ 431.51 Suspension of certification service.

When the Commissioner finds that a person has:

(a) Obtained or attempted to obtain a certificate through fraud or through misrepresentation or concealment of a material fact; or

(b) Falsified the records required to be kept by § 431.61; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to take an inventory of stocks on hand, or otherwise to check the correctness of such records as required by § 431.61; or

(d) Failed to establish a system for maintaining the records required by § 314.81 of this chapter or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of that section, or has refused to permit access to, or copying, or verification of such records or reports; or

(e) Failed to conform to the requirements of good manufacturing practice prescribed by parts 210, 211, 225, 226 and 229 of this chapter;

the Commissioner will immediately suspend service to such person under the regulations in this chapter. Upon request a hearing will be granted to such person to show cause why such service should be resumed.

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 55 FR 11582, Mar. 29, 1990]

§ 431.52 Hearings.

Any person who contests the suspension of certification service under § 431.51 shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15675, Mar. 22, 1977]

§ 431.53 Fees.

(a) Fees for the services rendered under the regulations in this chapter shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this chapter, shall be \$114 for each batch submitted, plus the sum of the fees for all individual tests required for certification of each batch. The minimum tests for each batch shall be those prescribed in the section relating specifically to such drug.

(1) The fee schedule for specific tests required for antibiotic drug certification is as follows:

CHARGEABLE FEE PER TEST	
Arquad content	\$20
Benzylpenicilloyl content	32
Bleomycin	1,291
Butanol content	52
Candidin potency (special turbidimetric)	85
Capreomycin 1 content	121
Color identity	8
Column chromatography	130
Column chromatographic isomer content	65
Copper content	22
Crystallinity	4
Cycloserine color assay	27
Daunorubicin potency (special turbidimetric)	19
Depressor substance test	40
Disc potency	52
Dissolution test	107
Doxycycline purity (paper chromatography)	130
Free chloride	54
Frozen antibiotic test panel	32
Gas chromatography	32
Gentamicin C	165
Heavy metals test	14
High pressure liquid chromatography (HPLC)	54
Infrared identity	19
Infrared quantitative	19
Iodochlorhydroxyquin content	22
Isoniazid content	22
Karl Fischer moisture	8
LD ₅₀ toxicity	185
Loss on drying	12
Lysine content	161
Melting range	8
Metal particles (ophthalmic ointments)	22
Microbiological assay, plate	50
Microbiological assay, turbidimetric	29